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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,179	06/20/2000	Maura Rooney	BSP2102US02	5883

22852 7590 06/03/2004

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/597,179

Applicant(s)

ROONEY ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,25,26,28-30 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,25,26,28-30 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 26 March 2004 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/26/04 has been entered.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 3/26/04 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 40, it is unclear how the cross-wound multifilar wire that consists of a coil in a first helical direction and a second coil in a second opposite helical direction (Applicant's Specification Page 7, lines 4 – 8) is considered a "unitary coil" as expressed in claim 22.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 22, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,622,184 to Ashby et al. in view of U.S. Patent No. 5,924,998 to Cornelius et al.

In regards to claims 22, 28 and 30, Ashby et al. discloses a guidewire including an elongate core (16) having a length, a proximal portion (18), and a distal portion (21); a continuous, unitary coil (30) composed of stainless steel (Col. 4, lines 23 – 26) surrounding a substantial portion of the length of the core and extending distal of the distal portion of the core (Col. 5, lines 15 – 19); and a polymeric tip (85; Col. 6, lines 54 – 57) extending from a distal portion of the coil. The tip (85) is connected to the core by a polymeric material (Col. 4, lines 63 – 67; Col. 6, lines 21 – 24). The distal portion of the core is tapered (Figure 4). Ashby et al. discloses the core being composed of stainless steel as well as other materials (Col. 4, lines 15 – 18). Ashby et al. fails to disclose the core being formed of a nickel-titanium alloy. However, Cornelius et al. discloses a guidewire wherein the core is composed of either stainless steel or a nickel-titanium alloy (Col. 3, lines 27 – 30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Ashby et al. to be composed of a nickel-titanium alloy as taught by Cornelius et al. in that Cornelius et al. discloses stainless steel and nickel-titanium alloy to be equivalent and therefore interchangeable.

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7. Claims 22, 25, 26, 30, 32 - 35, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,373,856 to Grenouillet in view of U.S. Patent No. 5,924,998 to Cornelius et al. and further in view of U.S. Patent No. 5,885,227 to Finlayson.

In regards to claims 22, 25, 26, 30, 32 - 35, 38 and 39, Grenouillet discloses a guidewire including an elongate core (2) having a length, a proximal portion (6), and a distal portion (8); a continuous, unitary coil (4) surrounding the entire length of the core and extending distal of the distal portion of the core (Col. 3, lines 27 - 32); and a tip (16) extending from a distal portion of the coil. The distal portion of the core is tapered (Figure 1). The coil comprises a multifilar wire having a pitch that varies at least once along the length (Col. 3, line 35 - Col. 4, line 3). The coil is shown to have a circular cross-section (Figure 1). Grenouillet discloses the core being composed of stainless steel (Col. 2, line 63). Grenouillet fails to disclose the core being formed of a nickel-titanium alloy. However, Cornelius et al. discloses a guidewire wherein the core is composed of either stainless steel or a nickel-titanium alloy (Col. 3, lines 27 - 30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Grenouillet to be composed of a nickel-titanium alloy as taught by Cornelius et al. in that Cornelius et al. discloses stainless steel and nickel-titanium alloy to be equivalent and therefore interchangeable. Additionally, Grenouillet fails to disclose the tip being a polymeric tip including radio-opaque material and being connected to the core by a polymeric material. Grenouillet also fails to disclose the coil having a lubricious coating. However, Finlayson discloses a guidewire having a polymeric tip (20) including radio-opaque material (Col. 3, lines 29 - 35) that is connected to the core by a polymeric material (Col. 4, lines 10 - 11). Finlayson also teaches the use of a lubricious coating on the coil (Col. 2, lines 55 - 59). It would have been obvious to modify the tip as disclosed by Grenouillet to be a polymeric tip including radio-opaque material connected to the core by a polymeric material as

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taught by Finlayson in order to secure the tip to the core to allow the tip of the guidewire to be seen with an imaging device while performing a medical procedure. It would have been obvious to provide the coil as disclosed by Grenouillet with a lubricious coating as taught by Finlayson to allow the wire to slide more easily through the arteries (Col. 2, lines 55 – 59).

8. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,373,856 to Grenouillet in view of U.S. Patent No. 5,924,998 to Cornelius et al. and further in view of U.S. Patent No. 5,885,227 to Finlayson as applied to claim 22 above, and further in view of U.S. Patent No. 5,947,940 to Beisel.

In regards to claim 29, Grenouillet in view of Cornelius et al. and Finlayson fails to disclose using a precipitation hardened alloy as the coil material. Beisel discloses a precipitation hardened alloy as the coil material for aiding guidewire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire of Grenouillet in view of Cornelius et al. and Finlayson to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

9. Claim 36 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,373,856 to Grenouillet in view of U.S. Patent No. 5,924,998 to Cornelius et al. and further in view of U.S. Patent No. 5,885,227 to Finlayson as applied to claim 34 above, and further in view of U.S. Patent No. 5,997,517 to Whitbourne.

In regards to claim 36, Grenouillet in view of Cornelius et al. and Finlayson discloses a polymeric coating, but fails to disclose the coating being colored. Whitbourne teaches the use of a colored coating with various medical devices such as guidewires to enhance the performance of the

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devices (Col. 4, lines 2 – 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Grenouillet in view of Cornelius et al. and Finlayson to include a colored coating as taught by Whitbourne to enhance the performance of the guidewire by assisting in the identification of the guidewire.

10. Claim 37 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,373,856 to Grenouillet in view of U.S. Patent No. 5,924,998 to Cornelius et al. and further in view of U.S. Patent No. 5,885,227 to Finlayson as applied to claim 22 above, and further in view of U.S. Patent No. 5,067,489 to Lind.

In regards to claim 37, Grenouillet in view of Cornelius et al. and Finlayson discloses a coil having a circular cross-section, but fails to disclose the coil comprising a rectangular cross-section. However, Lind discloses a guidewire wherein the coil has either a circular or rectangular cross-section (Col. 2, lines 56 – 63). It would have been obvious to one having ordinary skill in the art to modify the coil as disclosed by Grenouillet in view of Cornelius et al. and Finlayson to include a rectangular cross-section as taught by Lind in that Lind discloses the two cross-sections to be equivalent and therefore interchangeable.

Response to Arguments

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



JMLF
June 1, 2004


MARY BETH JONES
ACTING SUPERVISORY PATENT EXAMINER